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14D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/151,885 09/11/98 COSTIN

J 98-WL-1

004370
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HM22/0307

EXAMINER

LEE, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

03/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/151,885

Applicant(s)

Gordziel et al.

Examiner

Howard C. Lee

Group Art Unit
1623



☒ Responsive to communication(s) filed on Jan 19, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

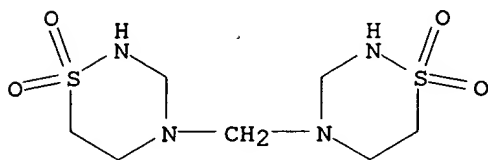
☐ Notice of Informal Patent Application, PTO-152

Howard C. Lee

Howard C. Lee
Primary Examiner
Art Unit 1623

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2000 ACS
 RN 19388-87-5 REGISTRY
 CN 2H-1,2,4-Thiadiazine, 4,4'-methylenebis[tetrahydro-, 1,1,1',1'-tetraoxide
 (8CI, 9CI) (CA INDEX NAME)
 OTHER NAMES:
 CN 4,4'-Methylenebis(perhydro-1,2,4-thiadiazin 1,1-dioxide)
 CN **Taurolidine**
 CN Taurolin
 CN Tauroline
 FS 3D CONCORD
 MF C7 H16 N4 O4 S2
 CI COM
 LC STN Files: ADISINSIGHT, AIDSLINE, ANABSTR, BEILSTEIN*, BIOBUSINESS,
 BIOSIS, CA, CANCERLIT, CAPLUS, CASREACT, CHEMLIST, CIN, DDFU, DRUGNL,
 DRUGU, DRUGUPDATES, EMBASE, IFICDB, IFIPAT, IFIUDB, IPA, MEDLINE,
 MRCK*, PHAR, PROMT, SPECINFO, TOXLINE, TOXLIT, USAN, USPATFULL
 (*File contains numerically searchable property data)
 Other Sources: EINECS**, WHO
 (**Enter CHEMLIST File for up-to-date regulatory information)



91 REFERENCES IN FILE CA (1967 TO DATE)
 2 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
 91 REFERENCES IN FILE CAPLUS (1967 TO DATE)

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Examiner's Notes: Although it is clear that the applicants intend to use taurolidine in their method of use claims, the chemical nomenclature for this compound is incorrect (see sheet attached to the end of this office action).

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/266,215; claims 1-3 of copending Application No. 09/265,640 and claims 1-3 of copending Application No. 09/266,095. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims encompass the scope of the claims of '215.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 112, first paragraph rejection

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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No arguments were presented in the amendment of 19 January 2000 to traverse the rejection of claim 2 under 35 U.S.C. 112, first paragraph and as such the rejection from the first office action remains of record.

35 U.S.C. 103(a) rejection

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Traub et al., (Chemotherapy, vol. 39: 322-330, (1993).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Traub et al. as stated above in view of Blenkarn et al. (Surgical Res. Commun., vol. 2: 149-155, (1987).

Applicant's arguments filed 19 January 2000 have been fully considered but they are not persuasive. The applicants argue that "taurolidine reduces the adherence of microorganisms via a chemical modification of outer surfaces such as fimbriae causing agglutination or disappearance of the structures." (page 2, midway through the "Remarks").

However, the arguments are not persuasive for two reasons. First, these limitations are not present in the claim language. The claims are directed toward "prevention of the development of antibiotic drug resistance" or "prevention of bacteria to bacteria transfer of plasmid materials" and the specification itself gives examples of show the use of taurolidine to treat an anti-biotic resistant strain of bacteria.

Second even if the limitations were in the claims, those limitations would amount to a disclosure of the mechanism by which taurolidine acts to treat anti-biotic resistant strains of bacteria. The mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. Also, "the recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention." *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) and *In re Dillon*, 919 F. 2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990).

Status of Claims

No claim is allowed. Claims 1-4 are rejected. The inclusion of SN: 09/265,640 and 09/266,095 in the provisional double patenting rejection at this time was due to those applications unavailability during the first office action. Furthermore, the applicants did not disclose these applications in any of their communications prior to this office action.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers and other useful information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard C. Lee whose telephone number is (703) 308-4626 and e-mail address is Howard.Lee@uspto.gov (NOTE: **The U.S PTO does not accept responsibility for the security of e-mail transmissions by the applicant(s)**). Thus, e-mail sent to an examiner should not include confidential information. For further details, see the PTO Internet Usage Policy which has been published in the Federal Register of 21 June 1999, volume 64, number 118.) The examiner can normally be reached on Monday-Friday 0700-1530 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more!

Howard C. Lee
Howard C. Lee
Primary Examiner
Art Unit 1623
7 March 2000